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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,448	08/07/2002	Lilian Fuchshuber	468452000200	1448

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EXAMINER

VENKAT, JYOTHSNA A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/069,448

**Applicant(s)**

FUCHSHUBER ET AL.

**Examiner**

JYOTHSNA A VENKAT Ph. D

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-10 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Receipt is acknowledged of amendment filed on 9/20/04. Claims 1-6, 8-10, and 12-16 are pending in the application and the status of the application is as follows;

1.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-6, 8-10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent '152 and WO 87/04617('617) and U. S. Patent 6,207, 694('694).

5. The patent "'152 does not teach the limitation added for the new claims 12-16.

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The patent '152 does not teach the limitations of claims 2-3 wherein the concentration of the bulking agent is greater than 20% or greater than 50% or the pharmaceutically active agent as antifungal agents of claims 9, 12 or the specific antifungal agent of claim 13 or the specific surfactant of claim 16. All the examples in the patent teach water content greater than 20 %. However the patent at col.2 suggests the water content less than 20%. This is obtained when one skilled in the art adds the higher values for active ingredient, anionic surfactant, and polyhydric alcohol. The WO document teaches the concentration of the bulking agent PEG as 40-80%. The WO document also teaches non- aqueous compositions. See the examples. The patent '694 teaches antidandruff compositions using the antifungal agent at the paragraph bridging cols. 2-3, and also the specific sodium laureth sulfate, specific antifungal agent of claim 13. The patent also teaches foam booster which is Betaine under example 1. With respect to claim 15 limitation optimizing the water content is within the ken of the skilled chemist.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of '152 and increase the concentration of the PEG of the patent to greater than 20% and combine with anti fungal agent for the control of dermal infection. The motivation to use higher concentration of PEG stems from the teaching of WO document that at higher concentration the PEG can dissolve the active ingredients so that better fungicidal properties are exhibited and the PEG also acts as penetration enhancer. This is a prima facie case of obvious ness.

### ***Response to Arguments***

Applicant's arguments filed 9/20/04 have been fully considered but they are not persuasive.

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6. Applicant's argue that the patent '152 teaches shampoo composition composed of 0.001% to 5% by weight of pyriproxyfen, 10% to 70% by weight of an anionic surfactant, 0.5% to 20% by weight of a polyhydric alcohol, and water as the balance, and point out that it is clear water was intended as the fourth constituent part of the formulation, i.e., the formulation was never intended to be a 3 component system as the examiner has contemplated. Applicants also argue that such a hypothetical formulation would probably be irritating to the skin, due to the high concentrations of active and submit Material Safety Data Sheet and point that the active ingredient is a skin irritant.

7. The examiner would like to point out to applicants once again that the patent indeed teaches 4 component system and if one would take the highest range for all the ingredients then the range for water as the 4<sup>th</sup> component would be less than 20%, i.e., by adding 5%, 70%, 20% the total percentage is 95% and the balance would be water which is 5%. Therefore the patent clearly teaches the concept of having water in the shampoo compositions, which is less than 20%. This concentration is claimed in the instant application as non-aqueous shampoo compositions. The examiner reviewed the material data sheet and the data sheet is with respect to the product Knack Insect growth regulator and not with respect to Pyriproxyfen (emphasis added), which has the concentration of the active ingredient at a range higher than the range taught by the patent '152.

8. Applicants argue that '617 reference does not supply the deficient teaching of the primary reference, because '617 teaches liquid compositions containing a combination of urea, lactic acid, and high amounts of propylene glycol (see, page 3, lines 10-21) and the '617 application teaches a formulation strong enough to penetrate the nail, and this nail penetration

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formulation is not a shampoo as is currently taught and claimed, and the '694 patents adds nothing to the already deficient teachings because '694 teaches aqueous shampoo compositions for dandruff (Examples 1 and 4), thinning hair (Examples 2 and 5), and chemically treated hair (Example 3) containing from 47% to 86.4% of added water and therefore none of the cited references teach or suggest the substantially non- aqueous liquid shampoo compositions as is presently claimed.

9. Examiner relied on '617 for the teaching of higher concentration of PEG and relied on '617 for the teachings of specific fungal agents in the shampoo compositions. Therefore one of ordinary skill in the art would be motivated to prepare compositions of '152 and increase the concentration of the PEG of the patent to greater than 20% and combine with anti fungal agent for the control of dermal infection(dandruff) because higher concentration of PEG can dissolve the active ingredients so that better fungicidal properties are exhibited and PEG also acts as penetration enhancer to the scalp. One of ordinary skill in the art would have reasonable expectation of success that by using less water and more PEG, PEG would dissolve the active ingredient (fungal agent) and the active ingredient would penetrate the scalp more effectively.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**JYOTHSNA A VENKAT Ph. D**  
**Primary Examiner**  
**Art Unit 1615**

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